REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks.

This Amendment is being filed together with a Request for Continued Examination in response to the Advisory Action issued on December 7, 2005.

Before addressing the outstanding prior art rejection, it is noted that the top of page two of the final Official Action indicates that copies of the two international application publications cited in the Information Disclosure Statement filed on August 4, 2003 were not submitted with the Information Disclosure Statement. However, as explained in the Request for Reconsideration filed on November 29, 2005, copies of the two international application publications can be found in the Patent Office's electronic database for this application. The undersigned telephoned Examiner Miggins on November 8, 2005 to discuss this matter. The undersigned explained that included amongst the electronic documents for this application in the Patent Office's PAIR system are the two international application publications submitted with the August 4, 2003 Information Disclosure Statement. Examiner Miggins checked the Examiner's version of the Patent Office's electronic database once again and indicated that the two international application publications are now present. Examiner Miggins thus asked the undersigned to submit a copy of the previously submitted Information Disclosure Statement and such documents would be considered. Thus, attached to the previously filed Request for Reconsideration was a copy of the First Information Disclosure Statement and accompanying form PTO-1449 filed on August 4, 2003. The Examiner is once again asked to return an initialed and signed copy of form PTO-1449.

The recently issued Advisory Action indicates that the rejection of Claims 1-11 based on the disclosure in International Application No. WO 01/34062 to *Chen et al.* is still proper in light of the discussion beginning in line 23 of page 7 and extending to page 8 of *Chen et al.* That position is respectfully traversed for the following reasons.

As has been discussed in prior responses, the subject matter recited in independent Claim 1 pertains to a balloon catheter comprising an elongated body and a balloon disposed on the distal side of the elongated body, with the balloon being made from a composite material composed of short-fibers for reinforcement and a matrix resin. Claim 1 also defines that the fibers are oriented in the balloon in such a manner that in a longitudinal cross-section of the balloon 25% or more of the fibers are oriented in the major-axis direction of the balloon, 25% or more of the fibers are oriented in the direction oblique to the major-axis direction, and the remaining short-fibers are oriented in the direction nearly perpendicular to the major-axis direction. In addition, in the diametrical cross-section of the balloon, 8% or more of the fibers are oriented in the circumferential direction of the balloon, 25% or more of the fibers are oriented in the direction perpendicular to the circumferential direction, and the remaining short-fibers are oriented in the direction oblique to the circumferential direction.

It is not clear from the Advisory Action if perhaps the Examiner might somehow be interpreting independent Claim 1 as only requiring, relative to the longitudinal cross-section of the balloon, short-fibers oriented in the major-axis direction of the balloon and short-fibers oriented in the direction oblique to the major-axis direction, and as only requiring, relative to the diametrical cross-section of the

balloon, short-fibers oriented in the circumferential direction of the balloon and short-fibers oriented in the direction perpendicular to the circumferential direction. In the event that is the case, Claim 1 has been amended to make clear that the short-fibers in the longitudinal cross-section of the balloon comprise short-fibers oriented in the major-axis direction of the balloon, short-fibers oriented in the direction oblique to the major-axis direction and short-fibers oriented in the direction nearly perpendicular to the major-axis direction, and that the short-fibers in the diametrical cross-section of the balloon include short-fibers oriented in the circumferential direction of the balloon, short-fibers oriented in the direction perpendicular to the circumferential direction, that is in a major-axis direction, and short-fibers oriented in the direction oblique to the circumferential direction.

Thus, Claim 1 clearly sets forth that the short-fibers are oriented in the balloon such that in the longitudinal cross-section of the balloon, there are: 1) short-fibers (25% or more) oriented in the major-axis direction of the balloon, 2) short-fibers (25% or more) oriented in the direction oblique to the major-axis direction; and 3) short-fibers (the remaining short-fibers) oriented in the direction nearly perpendicular to the major-axis direction. In addition, Claim 1 clearly sets forth that the short-fibers are oriented in the balloon such that in the diametrical cross-section of the balloon, there are: 1) short-fibers (8% or more) oriented in the circumferential direction of the balloon; 2) short-fibers (25% or more) oriented in the direction perpendicular to the circumferential direction, that is, in the major-axis direction; and 3) short-fibers (the remaining short-fibers) oriented in the direction oblique to the circumferential direction.

Turning now to the disclosure in *Chen et al.*, the description beginning at the bottom of page 7 states that the fibers in the balloon can be oriented diagonally relative to the longitudinal axis of the balloon. *Chen et al.* describes that a parison 60 for the balloon can be produced using a high puller speed and a counter rotating die (a mandrel rotating in one direction and a concentric outer die rotating in an opposite direction). The resulting parison includes fibers 62 oriented diagonally to the parison axis 64 in one direction at the outside surface (angle α) and changing gradually passing through the material in a direction transverse to the parison axis 64 to a second direction (angle β) at the inside surface. *Chen et al.* also describes that if one or the other of the outer die or the mandrel is held stationary while the other is rotated, the angle α or angle β may be parallel to the parison axis 64.

Based on the foregoing description in *Chen et al.*, the most that can be said about the disclosed balloon is that it includes, relative to a longitudinal cross-section, fibers oriented parallel to the parison axis (major-axis direction) and fibers oriented diagonal or oblique to the parison axis. However, there is no disclosure in *Chen et al.* that in the longitudinal cross-section of the balloon, short-fibers should also be oriented in the direction nearly perpendicular to the major-axis direction. Further, there exists absolutely no disclosure in *Chen et al.* stating that the fibers should be oriented in the balloon such that in a diametrical cross-section, there are fibers oriented in the circumferential direction of the balloon, fibers oriented in the direction perpendicular to the circumferential direction, and fibers oriented in the direction oblique to the circumferential direction. The Advisory Action does not address these deficiencies in *Chen et al.*

The Advisory Action does comment that the particular percentages recited in independent Claim 1 would have been obvious as involving a determination of the workable or optimum range for a result effective variable. Assuming for the sake of argument that it would have been obvious to "optimize" the percentages of fibers oriented in the direction parallel to the parison axis and diagonal to the parison axis as described in *Chen et al.*, the Examiner has not established that the "optimum" percentages for achieving the results sought to be achieved by *Chen et al.* are necessarily the same percentages as those claimed for achieving a completely different purpose. That is, as explained in prior responses and as discussed in the present application at, for example, the middle portions of pages 14 and 16, the balloon construction at issue here seeks to provide a balloon having improved hoop strength and longitudinal strength, and otherwise sufficient strength to withstand pressure that might otherwise contribute to the formation of pin-holes and cracks during balloon dilation.

In contrast, *Chen et al.* specifically seeks to provide a balloon having radial expansion capability, but little or no longitudinal expansion characteristics. *Chen et al.* notes the following in the discussion beginning in line 21 of page 2.

> The orientation of the fibril structure can limit longitudinal expansion of the balloon and allow the balloon to expand radially as desired, but minimally, or not at all in the longitudinal direction if the fibrils are parallel to the balloon axis, or when the fibrils are oriented diagonally about the axis, can limit both longitudinal and radial expansion of the balloon when inflated.

Thus, it is seen that the objective sought to be achieved by the particular construction of the balloon described in *Chen et al.* is quite different from that associated with the present invention. The Official Action has not established that the "optimum" percentages of fibers parallel and diagonal to the parison axis for

purposes of producing a balloon having radial expansion capability but little or no longitudinal expansion characteristics as described in *Chen et al.* are the same as the "optimum" percentages one would select for producing a balloon which is sufficiently strong to withstand pressure that might otherwise contribute to the formation of pin-holes and cracks during balloon dilation.

In addition, even if one were somehow motivated to "optimize" the percentages of fibers parallel and diagonal to the parison axis for purposes of producing a balloon having radial expansion capability but little or no longitudinal expansion characteristics as described in *Chen et al.*, there still exists no disclosure in *Chen et al.* that the balloon should also include fibers oriented in the direction nearly perpendicular to the major-axis direction, relative to the longitudinal cross-section of the balloon. Further, even if one were somehow motivated to "optimize" the percentages of fibers parallel and diagonal to the parison axis for purposes of producing a balloon having radial expansion capability but little or no longitudinal expansion characteristics as described in *Chen et al.*, there still exists no disclosure in *Chen et al.* that fibers should be oriented in the balloon such that in a diametrical cross-section, there are fibers oriented in the circumferential direction of the balloon, fibers oriented in the direction perpendicular to the circumferential direction, and fibers oriented in the direction oblique to the circumferential direction.

It is respectfully submitted that Chen et al. does not disclose a balloon having the claimed arrangement/orientation of fibers, and would not have led one of ordinary skill in the art to produce a balloon having the claimed arrangement/orientation of fibers. Accordingly, withdrawal of the rejection of record is respectfully requested.

In the event the Examiner continues to believe that the disclosure in *Chen et al.* is relevant to the claimed subject matter recited in independent claim 1, the Examiner is kindly asked to provide a detailed explanation of the portion of the disclosure in *Chen et al.* which describes fibers oriented in the particular manner recited in Claim 1.

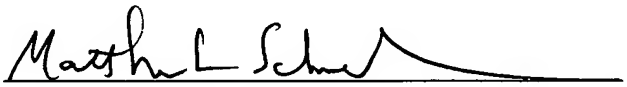
Early and favorable action with respect to this application is respectfully requested.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

BUCHANAN INGERSOLL PC

Date: December 23, 2005

By: 
Matthew L. Schneider
Registration No. 32,814

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620